K091828

Section 5:
510(K) Summary

(As required by 21 CFR 807.92)

Synthetic Polyisoprene Ultrasound Transducer Cover

September 25, 2009 (updated)

SEP 2 8 2009

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (WO66-0609)
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

To Whom it may Concern:
This letter, along with the attached materials is to notify your office of the intention of Sheathing Technologies to market the following device starting on or after (90) days from this date.

Device/Specification Developer:	Sheathing Technologies, Inc. 18431 Technology Drive Morgan Hill, CA 95037
Establishment Registration No.:	2950776
Contact Persons:	Richard Stevens Director of Product Development 1-408-782-2720 Jennifer Downing Manager of Quality & Research 1-408-782-2720
Trade Name:	SheathesISO Ultrasound Transducer Covers
Common Name:	Ultrasound Transducer Cover/Sheath/Drape
Classification Name:	Ultrasonic Diagnostic Transducer Accessories

Equivalence:

510(K) K013721, Synthetic Polyisoprene Ultrasound Transducer Cover, Civco Medical Instruments
510(K) K991236, NeoFlex™ Ultrasound Transducer Cover, Civco Medical Instruments

Labeling and Usage:

The following information will be found on each box/bag . (See Attachment E):

1. Proprietary name
2. Quantity of sheathes packed
3. Name and Location of Manufacturer
4. Sterile/NS (if applicable)
5. Expiration date
6. Size of probe cover
7. Caution statements: Follow manufacturer's instructions for cleaning and disinfecting the transducer.
8. Prescription Statement: "Caution: Federal law restricts this device to sale by or on the order of a physician or a practitioner trained in its use."

Device Description:

The Sheathing Technologies, Inc CIS-Isoprene Ultrasound Transducer Cover provides a thin, conformal covering to fit various and specific ultrasound transducer shapes. The cover is made by dipping to form a general cylindrical shape. It is closed at the proximal end and open at the distal end for insertion of the ultrasound transducer. This device is an accessory used on diagnostic probes to help minimize cross contamination.
The cover material is a Cis-1,4-polyisoprene, a synthetic version of natural rubber latex made without using natural rubber latex in the formulation. Various sizes and shapes of covers are offered to address the variations in Ultrasound Transducer configurations.

Product categories/models include

1. General Purpose SheathesISO Ultrasound Transducer Covers (sterile and non-sterile)

Covers are packaged in both sterile and non-sterile, individually wrapped or in bag/box quantities, as well as in "procedure kit" form for single patient/procedure, disposable use. The "procedure kit" may include elastic fasteners, with or without coupling gel packets. Transducer covers are also combined with disposable needle guide devices into kits.

Substantial Equivalence:

The Sheathing Technologies, Inc. CIS-Polyisoprene Ultrasound transducer cover is identified as substantially equivalent to CIVCO's current, legally marketed NeoFlex™ Ultrasound Transducer Covers and CIVCO's Synthetic Polyisoprene Ultrasound Transducer Cover.

Non-Clinical Tests:

1. Bench Testing:
   a. Viral Penetration Testing
   b. Stretch testing
   c. Pinhole testing
   d. Gel Compatibility
2. Biocompatibility
   a. Material Mediated Pyrogen
   b. Cytotoxicity
   c. Systemic Toxicity
   d. Hemolysis
   e. Irritation
   f. Sensitization

Conclusions from Non-Clinical Tests:

Sheathing Technologies's CIS-Polyisoprene ultrasound transducer cover is compatible with ultrasound gel, has sufficient strength and elasticity for the intended application, and is biocompatible according to the ISO 10993-1:2003 biocompatibility standard for a surface-contacting device that is in contact with the body for less than 24 hours.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Jennifer Downing
Manager of Quality & Research
Sheathing Technologies, Inc.
18431 Technology Drive
MORGAN HILL CA 95037

SEP 2 8 2009

Re: K091828
Trade/Device Name: SheathesISO Ultrasound Transducer Covers
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasound transducer
Regulatory Class: II
Product Code: ITX
Dated: August 28, 2009
Received: September 1, 2009

Dear Ms. Downing:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4:
Indications for Use Statement

510(k) Number (if known): K091828

Device Name: SheathesISO Ultrasound Transducer Covers

Indication For Use: Synthetic polyisoprene probe covers are indicated for use during diagnostic ultrasound procedures in cases where patient sensitivity to natural rubber latex is speculative.

Prescription Use X And/Or Over the Counter Use ___
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K091828